K063728

ATT 4

APR 4 - 2007

Exhibit #1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0 (k) numbers is:_____

1. **Submitter's Identification:**

Alfa Tech Medical Systems Ltd.
5A Kaf Tet Be November St. Apt. 29
Ramat Hanassi, Bat-Yam
Israel

Date Summary Prepared: March 12, 2007

Contact Persons:

Mr. Ilan Feferberg
COO
Alfa Tech Medical Systems, Ltd.
5A Kaf Tet Be November St. Apt. 29
Ramat Hanassi, Bat-Yam
Israel
Tel: + 972-3 5049039
Fax: + 972-3 5049039
E-mail: imft@zahav.net.il

Mr. Yossi Ben David
Alfa Tech QA Manager
Tel: + 972-9 7711018
Fax: + 972-9 7711019
E-mail: yossi@ordos.co.il

2. **Name of the Device:**

a. TRADE NAME: The TNN-DU810 Non-Invasive Subdermal Therapy System
b. CLASSIFICATION NAME: Ultrasonic Diathermy/Muscle Stimulator/Therapeutic Massager

3. **Common or Usual Name**: Ultrasound Diathermy/Powered Muscle Stimulator and Therapeutic Massager.

4. **Predicate Devices Information:**

- AlfaTech Medical Systems, Ltd. The DU857 Dual Frequency Ultrasound Therapy and Muscle Stimulator System, K#052340.
- Sybaritic Inc., Dermosonic Non-Invasive Subdermal Therapy System, K#024307.

5. **Device Description**:

The TNN-DU810 Non-Invasive Subdermal Therapy System is comprised of the following main components:

- A system console including software and control electrodes;
- A control and display panel;
- Device accessories including muscle stimulator electrodes (ME2221, Mettler Corp., K#013192) and cables, ultrasound transducers (applicators) (ME7513, Mettler Corp.) acoustic gel (Sonigel, Mettler Corp). and cables. The electrodes, ultrasound transducers and acoustic gel have all been cleared under the Mettler Electronics Corp. 510(k). Also included is a Dermosonic vacuum treatment roller head, cleared under the Dermosonic device, K024307.

The TNN-DU810 device has dual frequencies ultrasound therapy, muscle stimulator systems and therapeutic vacuum massager.

The user friendly interface comprises keyboard, touch screen and audio feedback. The screen provides operator information about operation mode and signal intersities. Large control knobs on the touch screen make adjusting power for ultrasound and muscle stimulation.

The system consists of the Alfatech DU857 device (K#052340) and the Dermosonic Therapeutic Vacuum Applicator, a component cleared in the Dermosonic K#024307..

The frequency Ultrasound Therapy, Muscle Stimulator System is identical to the DU857. It is important to note that there is no electric connection between the ultrasound therapy, muscle stimulator system and the therapeutic vacuum massager.

Each of the two components of the system (ultrasound plus neuromuscular stimulation) and the therapeutic massager function independently and have no connection between them.

6. **Intended Use:**

Therapeutic Ultrasound:

1. Pain relief
2. Reduction of muscle spasm
3. Localized increase of blood flow
4. Increase range of motion of contracted joints using heat and stretch techniques

Neuromuscular Stimulation:

1. Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute surgical pain
2. Temporary relaxation of muscle spasm
3. Prevention of post-surgical phlebo-thrombosis through immediate stimulation of calf muscles
4. Increase of blood flow in the treatment area.
5. Prevention or retardation of disuse atrophy in post-injury type conditions
6. Muscle re-education
7. Maintaining or increasing range of motion

Therapeutic Massager:

1. Relieves muscle spasms
2. Provides temporary relief of minor muscle aches and pains
3. Temporarily improves local blood circulation
4. Temporarily reduces the appearance of cellulite

7. Comparison to Predicate Devices:

Comparison of technological characteristics to a legally marketed predicate device is given in the table below:

Table 1. Comparison of general characteristics to legally marketed predicate Dermosonic Non-Invasive Subdermal Therapy System:

System.

Item for comparison	Claimed device	Predicate device 2
510K #	K052340	K024307
Device Name	TNN-DU810 Non-Invasive Subdermal Therapy System,	Dermosonic Non-Invasive Subdermal Therapy System
Intended use	Therapeutic vacuum Massager, Ultrasonic Diathermy and neuromuscular stimulation, including: temporarily improvement local blood circulation and temporarily reduction the appearance of cellulite	Therapeutic vacuum Massager and Ultrasonic Diathermy, including: temporarily improvement local blood circulation and temporarily reduction the appearance of cellulite
Design	1 model 2 ultrasound applicators 4 conductive electrodes 1 vacuum treatment roller head	1 model 1 ultrasound applicators 3 vacuum treatment roller head
Specifications	Ground current leakage <40 micamp.	Not specified
Performance	Use friendly interface, easy to operate	Use friendly interface, easy to operate
Frequency	1 MHz±5% 3 MHz±5%	1 MHz±3% 3 MHz±3%
Modes	Continuous	Continuous Pulsed – 5% duty cycle Pulsed – 10% duty cycle Pulsed – 20% duty cycle
Maximum Intensity	1.5 W/cm^2	2 W/cm^2
Maximum Treatment Time	30 minutes – ultrasound 30 minutes – electrical stimulation 40 minutes – suction treatment	30 minutes – ultrasound therapy 99 minutes – suction treatment
Classification	Protective Class I Equipment	Protective Class I Equipment
Type of applied part	BF type	BF type
Vacuum treatment mode	Continuous or pulsed	Continuous or pulsed
Depression level	Pulse mode -820 mbar maximum continuous mode- 125-210mbar	Pulse mode -820 mbar maximum continuous mode- 125-210mbar
Vacuum treatment roller head	61.452 - Dermasonic	61.452 – Dermasonic
	Each of the two components of the system (ultrasound+ Neuromuscular Stimulation) and the Therapeutic Massager function independently and have no connection between them.	Each of the two components of the system (ultrasound) and the Therapeutic Massager function independently and have no connection between them.
Relaxation time	0.36, 0 72, 1.08 or 1.44 sec	0.36, 0 72, 1.08 or 1.44 sec
Suction time	: 0.36, 0.72, 1.08, 1.44, 1.80. 2.16, 2.52, 2.88 or 3.24 sec	: 0.36, 0.72, 1.08, 1.44, 1.80. 2.16, 2.52, 2.88 or 3.24 sec

Vacuum Pressure	55, 80. 105, 125, 145. 160.185, 210, 240, 260. 260, 280 ,310, 330, 365,440, 510. 615, 715 or 820 Mbar	55, 80. 105, 125, 145. 160.185, 210, 240, 260. 260, 280 , 310, 330, 365,440, 510. 615, 715 or 820 Mbar
Air Flow	3500 l/hour	3500 l/hour
Treatment time - therapeutic vacuum massager	1 to 99 minutes	1 to 99 minutes

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence as follows:

Performance testing to include: Air Flow Testing, Vacuum Pressure Testing, Timer Testing, etc. Also conducted: Electrical Safety Testing, EMC Testing, Risk Analysis, etc.

9. Discussion of Clinical Tests Performed:

Not Applicable

10. Conclusions:

The subject TNN-DU810 device is substantially equivalent to the predicate device (K#024307) in design and function, (using the predicate's own rollers and vacuum suction components) thereby achieving increased blood flow and therefore achieving temporary reduction in the appearance of cellulite.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 4 - 2007

Alfa Tech Medical Systems, Ltd.
% MDI Consultants, Inc.
Ms. Susan D. Goldstein-Faulk
Official Correspondent
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K063728
Trade/Device Name: TNN-DU810 Subdermal Therapy System
Regulation Number: 21 CFR 890.5860
Regulation Name: Ultrasound and muscle stimulator
Regulatory Class: Class II
Product Code: IMG, IMI, IPF, LIH and ISA
Dated: March 15, 2007
Received: March 16, 2007

Dear Ms. Goldstein-Faulk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K063728 Page 1 of 1

Device Name: The TNN-DU810 Non-Invasive Subdermal Therapy System

Indications For Use:

Therapeutic Ultrasound:

1. Pain relief
2. Reduction of muscle spasm
3. Localized increase of blood flow
4. Increase range of motion of contracted joints using heat and stretch techniques

Neuromuscular Stimulation:

1. Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute surgical pain
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5. Prevention or retardation of disuse atrophy in post-injury type conditions
6. Muscle re-education
7. Maintaining or increasing range of motion

Therapeutic Massager:

1. Relieves muscle spasms
2. Provides temporary relief of minor muscle aches and pains
3. Temporarily improves local blood circulation
4. Temporarily reduces the appearance of cellulite

Prescription Use __X__ OR **Over-The Counter Use_____**
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063728